

REMARKS

Status of Claims

Claims 1-30 are pending. No claims have been canceled. The status of all claims, as of the date of this amendment, is reflected in Appendix A.

Claim Amendments

Independent claims 1 and 8 have been amended to recite (-)-gossypol as supported by the specification at, for example, column 7, lines 29-66. Claims 4 and 11 (depending from claims 1 and 8, respectively) have been amended to recite a blood level of “200-1000 ng/dl” of the compounds recited in claims 1 and 8, respectively, as supported by the specification at, for example, column 7, Table 4. New claims 15-30 have been added as supported by the specification at, for example, column 2, lines 20-25, and column 7, lines 29-34. Specifically, claims 15 and 16, depending from claims 1 and 8, respectively, further recite that the cancer is a carcinoid tumor of neuroendocrine tissue located in the lung, pancreas, or gastrointestinal tract. Independent claims 17 and 24 are identical in scope to original claims 2 and 9, respectively, except that claims 17 and 24 further recite that the cancer is a carcinoid tumor of neuroendocrine tissue located in the lung, pancreas, or gastrointestinal tract. Dependent claims 18-23 and 25-30 mirror original claims 2-7 and 9-14, respectively. The amended claims and the newly added claims, therefore, narrow the scope of the originally issued claims. Thus, the reissue application is a narrowing reissue.

The prior art reference, Yerukhimov et al., “Treatment of Bladder Tumors with Gossypol and Ionol in Combination with Surgical Intervention,” *Voprosy Onkologii* XII (1966), discloses the post-operative administration of racemic gossypol to patients, following surgical resection of bladder tumors. The Yerukhimov reference does not teach the use of alternative forms or isomers of gossypol. The Yerukhimov reference also does not teach, let alone suggest, that gossypol, more specifically (-)-gossypol, can be used to treat any other type of cancer. Thus, the subject matter defined by the amended and new claims is novel and

In re Appln. of Flack et al.
Application No. Unassigned

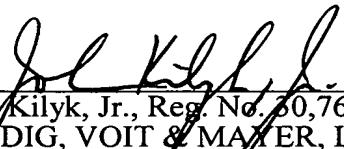
non-obvious in view of the Yerukhimov reference, even if considered in combination with other references as discussed below.

In addition to the Yerukhimov reference, other references became known to patentee after issuance of the subject patent. The newly identified references, along with the previously identified references, are presented in the Information Disclosure Statement submitted herewith. The previously identified references were identified during the original prosecution of U.S. Patent No. 6,114,397, and include references AG, BD, BK, BL, BN, BP, and BT. Although at least some of the newly identified references refer to gossypol, the references do not render obvious the invention defined by the amended and new claims, whether considered alone or in combination with the Yerukhimov reference.

Conclusion

The reissue application is considered to be in good and proper form for allowance, and the Examiner is respectfully requested to pass this reissue application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of this reissue application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



John Kilyk, Jr., Reg. No. 30,763
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson Avenue
Chicago, Illinois 60601-6780
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

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CLAIM STATUS – APPENDIX A

1. (Pending – Once Amended) A method for treating a cancer in a human, wherein the cancer is susceptible to treatment with (-)-gossypol, a physiologically acceptable salt of (-)-gossypol, gossypolone, a physiologically acceptable salt of gossypolone, or any combination thereof, which method comprises:

administering to said human an anti-cancer effective amount of at least one compound selected from the group consisting of (-)-gossypol, a physiologically acceptable salt of (-)-gossypol, gossypolone, and a physiologically acceptable salt of gossypolone, and a pharmaceutically acceptable carrier.

2. (Pending – Never Amended) The method of claim 1, wherein said cancer is adrenal, ovarian, thyroid, testicular, pituitary, prostate, or breast cancer.

3. (Pending – Never Amended) The method of claim 2, wherein said cancer is adrenal cancer.

4. (Pending – Once Amended) The method of claim 1, wherein the blood concentration of said compound is 200-1000 ng/dl.

5. (Pending – Never Amended) The method of claim 4, wherein said compound is gossypolone or a physiologically acceptable salt of gossypolone.

6. (Pending – Never Amended) The method of claim 5, wherein said gossypolone or physiologically acceptable salt of gossypolone is administered orally, rectally or vaginally at a dose of 50-200 mg/d.

7. (Pending – Never Amended) The method of claim 5, wherein said gossypolone or physiologically acceptable salt of gossypolone is administered parenterally at a dose of 1-5 mg/kg/d.

8. (Pending – Once Amended) A method for treating a cancer in a human, wherein the cancer is susceptible to treatment with (-)-gossypol, a pharmaceutically acceptable salt of (-)-gossypol, or a combination thereof, which method comprises:
administering to said human an anti-cancer effective amount of at least one compound selected from the group consisting of (-)-gossypol and a physiologically acceptable salt thereof, and a pharmaceutically acceptable carrier.
9. (Pending – Never Amended) The method of claim 8, wherein said cancer is adrenal, ovarian, thyroid, testicular, pituitary, prostate, or breast cancer.
10. (Pending – Never Amended) The method of claim 8, wherein said cancer is adrenal cancer.
11. (Pending – Once Amended) The method of claim 8, wherein the blood concentration of said compound is 200-1000 ng/dl.
12. (Pending – Never Amended) The method of claim 8, wherein said compound is administered parenterally at a dose of 1-2 mg/d.
13. (Pending – Never Amended) The method of claim 8, wherein said compound is administered orally at a dose of 20-100 mg/d.
14. (Pending – Never Amended) The method of claim 8, wherein said compound is administered rectally at a dose of 40-140 mg/d.
15. (Pending – Newly Added) The method of claim 1, wherein said cancer is a carcinoid tumor of neuroendocrine tissue located in the lung, pancreas, or gastrointestinal tract.

16. (Pending – Newly Added) The method of claim 8, wherein said cancer is a carcinoid tumor of neuroendocrine tissue located in the lung, pancreas, or gastrointestinal tract.

17. (Pending – Newly Added) A method for treating a cancer in a human, wherein the cancer is susceptible to treatment with gossypol, a physiologically acceptable salt of gossypol, gossypolone, a physiologically acceptable salt of gossypolone, or any combination thereof, which method comprises:

administering to said human an anti-cancer effective amount of at least one compound selected from the group consisting of gossypol, a physiologically acceptable salt of gossypol, gossypolone, and a physiologically acceptable salt of gossypolone, and a pharmaceutically acceptable carrier, wherein said cancer is adrenal, ovarian, thyroid, testicular, pituitary, prostate, or breast cancer, or said cancer is a carcinoid tumor of neuroendocrine tissue located in the lung, pancreas, or gastrointestinal tract.

18. (Pending – Newly Added) The method of claim 17, wherein said cancer is adrenal, ovarian, thyroid, testicular, pituitary, prostate, or breast cancer.

19. (Pending – Newly Added) The method of claim 18, wherein said cancer is adrenal cancer.

20. (Pending – Newly Added) The method of claim 17, wherein the blood concentration of said compound is 400-1000 ng/dl.

21. (Pending – Newly Added) The method of claim 20, wherein said compound is gossypolone or a physiologically acceptable salt of gossypolone.

22. (Pending – Newly Added) The method of claim 21, wherein said gossypolone or physiologically acceptable salt of gossypolone is administered orally, rectally or vaginally at a dose of 50-200 mg/d.

23. (Pending – Newly Added) The method of claim 21, wherein said gossypolone or physiologically acceptable salt of gossypolone is administered parenterally at a dose of 1-5 mg/kg/d.

24. (Pending – Newly Added) A method for treating a cancer in a human, wherein the cancer is susceptible to treatment with gossypol, a pharmaceutically acceptable salt of gossypol, or a combination thereof, which method comprises:

administering to said human an anti-cancer effective amount of at least one compound selected from the group consisting of gossypol and a physiologically acceptable salt thereof, and a pharmaceutically acceptable carrier, wherein said cancer is adrenal, ovarian, thyroid, testicular, pituitary, prostate or breast cancer, or said cancer is a carcinoid tumor of neuroendocrine tissue located in the lung, pancreas, or gastrointestinal tract.

25. (Pending – Newly Added) The method of claim 24, wherein said cancer is adrenal, ovarian, thyroid, testicular, pituitary, prostate, or breast cancer.

26. (Pending – Newly Added) The method of claim 25, wherein said cancer is adrenal cancer.

27. (Pending – Newly Added) The method of claim 24, wherein the blood concentration of said compound is 400-1000 ng/dl.

28. (Pending – Newly Added) The method of claim 24, wherein said compound is administered parenterally at a dose of 1-2 mg/d.

29. (Pending – Newly Added) The method of claim 24, wherein said compound is administered orally at a dose of 20-100 mg/d.

30. (Pending – Newly Added) The method of claim 24, wherein said compound is administered rectally at a dose of 40-140 mg/d.